REMARKS

Claims 1-7, 15-18, 20-28, 31, 34, 35 and 37-41 are pending in the instant application. Claims 1-7, 15-18, 20-28, 31, 34, 35 and 37-41 have been rejected. Claims 1, 2, 3, 4, 5, 6, 7, 16, 17 20, 21, 35, 37 and 39 have been amended. Claim 15 has been canceled in light of these amendments. Support for these amendments is provided in the specification at page 10, lines 5-9, pages 16, 17, 28, 29 and 30 and the Examples beginning at page 31. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Sequence Listing

The instant application is suggested to fail to comply with the sequence listing requirements of 37 C.F.R. 1.821 through 1.825. Specifically, sequences recited in the specification in Table 1 are suggested by the Examiner to not be identified be a sequence identification number.

It is respectfully pointed out, however, that this Table was amended to include Sequence Identifiers on August 30, 2001. Further, Applicants responded to two Notices to Comply received thereafter on December 18, 2001 and August 14, 2002. Courtesy copies of each of these responses are

provided herewith. Applicants believe that further amendment is not required.

Withdrawal of this objection is respectfully requested in light of these prior filed amendments.

II. Rejection of Claims 1-7, 15-18, 20-28, 31, 34-35 and 37-41 under 35 U.S.C. 112, first paragraph

Claims 1-7, 15-18, 20-28, 31, 34-35 and 37-41 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. In particular, the Examiner suggests that the specification does not teach the measurement of normal or healthy values for the claimed protein markers nor establish individual control ranges to compare the measure against the detected myofilament protein modification proteins as a measure of muscle damage.

Further, while the Examiner has acknowledged the specification to be enabling for the detection of troponin I, troponin T, troponin C, α-actinin, actin, tropomyosin, desmin, myosin light chain 1, myosin light chain 2 and myosin light chain 3 myofilament chemical adduct modification products occurring post-translationally in cardiac muscle, the Examiner suggests that it does not reasonably provide enablement for any and all muscle damage.

Applicants respectfully traverse these rejections.

As taught at page 11 of the instant specification, the present invention is based, in part, on the recognition that myofilament protein modification products are produced in a progressive and selective manner depending on the severity and nature of the ischemic/hypoxic insult, such that specific forms of myofilament protein modification products in a biological sample have diagnostic utility. Thus, detecting presence alone of these myofilament protein modification products in a biological sample obtained from a patient is useful in assessing muscle damage. Detailed teachings of detecting the presence and correlating this presence with assessment of muscle damage of various myofilament protein modification products of TnI, TnT, TnC, α-actinin and MLC1 are provided in the specification at pages 16, 17, 28, 29 and 30 as well as in the Examples beginning at page 31. In an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to myofilament protein modification products of TnI, TnT, TnC, α-actinin and MLC1. Applicants believe these teachings in the specification provide one of skill in the art with adequate guidance to make and use the invention as now claimed thus meeting the enablement requirements of 35. U.S.C. 112, first paragraph. Further guidance with

respect to control values are not needed when presence alone of a myofilament protein modification product of TnI, TnT, TnC, α-actinin or MLC1 is clearly demonstrated in the specification to be useful in assessing muscle damage.

Applicants have also amended the claims to specify that the methods assess cardiac and skeletal muscle damage. The Examiner has acknowledged that the disclosure exemplifies heart related tissue assessment. Applicants respectfully direct the Examiner to page 10, lines 5-10 of the instant specification wherein the similar or overlapping pathways for muscle damage of cardiac and skeletal muscle are set forth. These teachings clearly provide one of skill in the art with the ability to practice this aspect of the present invention as well without undue experimentation, thus also meeting the enablement requirement of 35 U.S.C. 112, first paragraph.

Withdrawal of these rejections under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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